UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,705	03/30/2004	J. Richard Gyory	ALZA-0377/ALZ5016USANP	7214

45511 7590 09/18/2009

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
09/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/814,705
Filing Date: March 30, 2004
Appellant(s): GYORY, J. RICHARD

Jane E. Inglese (Reg. No. 48,444)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/14/2009 appealing from the Office action mailed 1/8/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Rejection of claim 22 as being indefinite under 35 U.S.C. 112(2^{nd}) paragraph due to insufficient antecedent basis has been hereby withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,857,994	Flower	1-1999
6,915,159	Kuribayashi et al	7-2005

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the appellant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the appellant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 17-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flower (5857994). Flower discloses an electrotransport device (Fig 1) comprising: a reservoir and a non-conductive housing (4) for the reservoir that comprising a substantially flexible electrically conductive element (8, 26) integrally molded within the non-conductive housing (Fig 1-2, wherein the housing 4 is shown by the dotted lines in Fig 2 and the conductive element is shown outside the housing 26 and entering the housing 4 to contact 8), the electrically conductive element comprising an electrode end (8) positioned within the non-conductive housing and coated with an electrode coating (8; wherein the Examiner notes that Webster's defines a coating as a layer of one substance covering another - in the present instance the electrode end (8) is formed by a layer of conductive material placed

within a patch layer (4) and on top of a layer (12)); a connecting portion (26) coating with a connecting coating comprising a flexible polymer containing conductive particles (wherein an electrically conductive adhesive is a flexible polymer containing conductive particles allowing electrical communication and that is a layer of substance covering part of the patch (4) meeting the definition of a coating); and a contact end positioned outside the non-conductive housing and coated with a contact coating (34; wherein the patch tab pads are outside the non-conductive housing and have a layer of conductive material that conducts with electrical terminals (38)); and wherein a substantially liquid and moisture-impermeable bond is created between the material forming the non-conductive housing and the conductive element (Fig 1-2; col 4, lns 18-24, 36-44); wherein the non-conductive housing is a single integral component (4, Fig 1, 2); wherein the electrotransport device is manufactured without the fabrication of openings or other passages through the non-conductive housing (4, Fig 1, 2); wherein the conductive element comprises a substantially planar member (26, Fig 1); wherein the conductive element includes a base member having a conductive coating disposed thereon (26; Fig 1, col 4, lns 28-31).

3. Flowers does not explicitly disclose that the conductive elements (8, 26) and the non-conductive housing (4) form a substantially liquid and moisture-impermeable bond. However, it would be obvious to one of ordinary skill in the art at the time the invention was made to the seal between the conductive elements (8,26) and (4) inherently has substantially liquid and moisture-impermeable characteristics (see MPEP 2112). It is clear that the housing is substantially liquid and moisture impermeable because the housing contains liquid therapeutic agents, saline, or conductive gels (col 4, lns 18-24, 36-44). Additionally, it is clear that the electrical connectors (8, 26) are housed both inside the housing (8, 26) and external to the housing (26; discussion

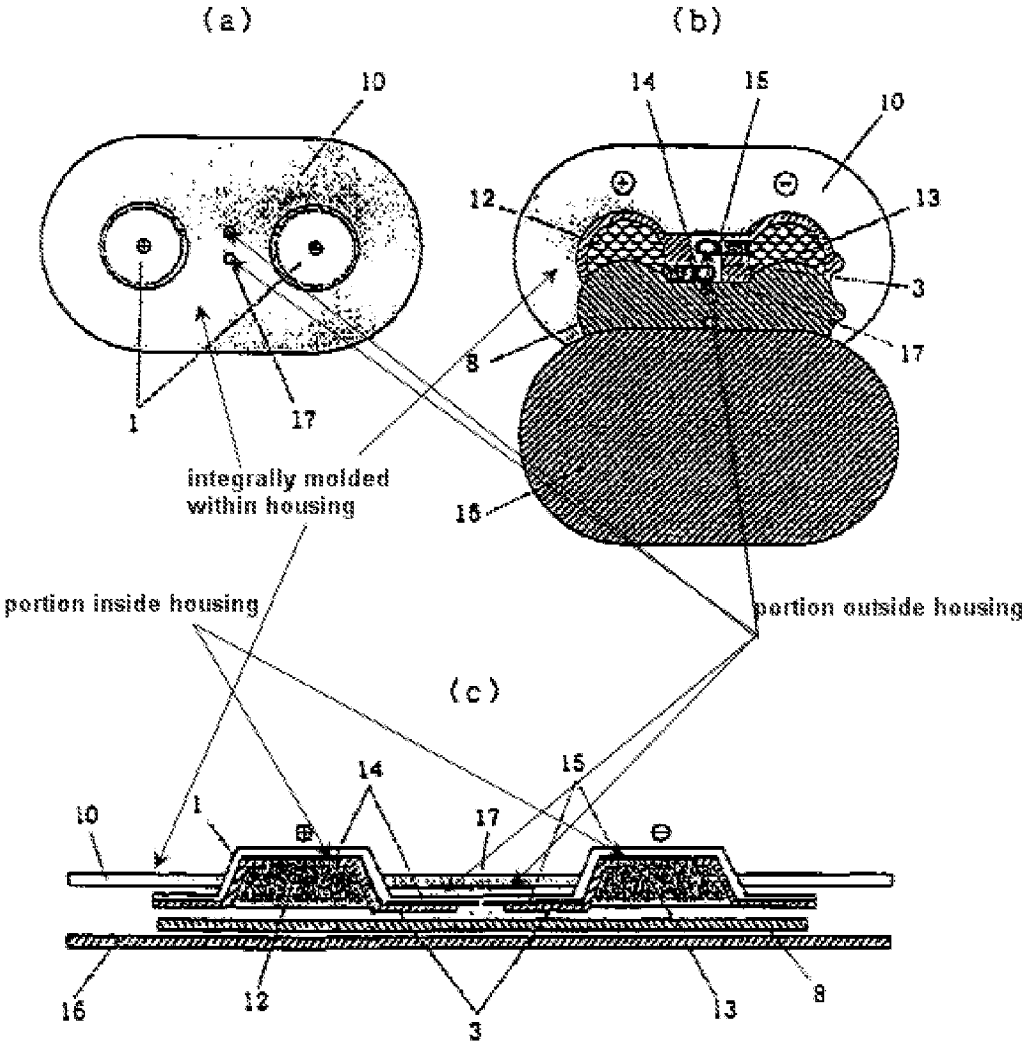
above). As shown in Figs 1-2, the electrical connectors (8 and 26) are clearly sealed into housing 4 and as electrical connectors (26) travel to tab (32) and connect with exposed connector (34). Since the electrical connectors (8, 26) contact the non-conductives and the liquid therapeutic agents, saline, or conductive gels housed therein and additional travel outside the housing to tab (32) and exposed connector (34) and this occurs via a seal between the housing and the electrical connectors and result in no leaking or loss of non-conductive fluid, it is obvious and necessarily flows from Flowers that the seal/bond created between the material forming the non-conductive housing and the conductive element is substantially liquid and moisture-impermeable.

4. Claims 17-22 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuribayashi et al (6915159). Kuribayashi et al discloses an electrotransport device (Fig 1-12) comprising: a non-conductive non-conductive housing for the non-conductive of the electrotransport device comprising a substantially flexible electrically conductive element (2, 14, 15, Fig 1a-c, 5a-b, 6a-c) integrally molded within the non-conductive housing (1), the electrically conductive element comprising an electrode end (portion of 2, 12 and 13 identified as being within the housing in the annotate figure below; again the Examiner notes that a coating is simply a layer of one substance on another - in the instant case, conductive elements 2 – near reference numerals 12, 13 are placed over a backing 1 as a coating which is disclosed as being made via a conductive ink) positioned within the non-conductive housing and coated with an electrode coating; a connecting portion (portions of 2 connecting the areas between reference numbers and arrows 14 and 15 in the annotated figure below) coating with a

connecting coating comprising a flexible polymer (col 8, lns 50-col 9, lns 15); and a contact end positioned outside the non-conductive housing and coated with a contact coating (14, 15, 17 as identified as the portion outside the housing – col 18, lns 1-16 and discussions

above).

Fig. 6



5. Further, wherein a substantially liquid and moisture-impermeable bond is created between the material forming the non-conductive housing and the conductive element (Fig 1a-c,

5a-b, 6a-c, 8; col 3, lns 20-25, 53-55, 60-col 4, lns 5, lns 12-14, 44-46; col 5, lns 59-64, col 6, lns 6-9, lns 28-39; col 7, lns 63-65; col 8, lns 13-16; col 19, lns 20-57; and col 21, lns 42-45; and discussion below); wherein the non-conductive housing is a single integral component (1; Figs 1, 5a-d, 6a-c, 8); wherein the electrotransport device is manufactured without the fabrication of openings or other passages through the non-conductive housing (Figs 1, 5a-d, 6a-c, 8); wherein the conductive element comprises a substantially planar member (2, 14, 15; Figs 1, 5a-d, 6a-c, 8); wherein the conductive element includes a base member having a conductive coating disposed thereon (col 7, lns 1-5, 39-47).

6. Kuribayashi et al does not explicitly disclose that the conductive elements (2, 14, 15) and the non-conductive housing (1) form a substantially liquid and moisture-impermeable bond. However, it would be obvious to one of ordinary skill in the art at the time the invention was made to the seal between the conductive elements (2, 14, 15) and (1) inherently has substantially liquid and moisture-impermeable characteristics (see MPEP 2112). First, the teachings of Kuribayashi et al (Fig 1a-c, 5a-b, 6a-c, 8; col 3, lns 20-25, 53-55, 60-col 4, lns 5, lns 12-14, 44-46; col 5, lns 59-64, col 6, lns 6-9, lns 28-39; col 7, lns 63-65; col 8, lns 13-16; col 19, lns 20-57; and col 21, lns 42-45) clearly disclose a desire and capability for substantially liquid and moisture-impermeable seals between components to maintain proper drug stability and sealing of the conductive layers. Explicitly disclosed is the fact that the materials used in constructing the non-conductive housing are water-impermeable materials, water-proof, and oil proof. Additionally, explicitly disclosed it the fact that a water evaporation test that tested the devices ability to maintain liquid within the non-conductive housing without evaporation loss resulted in nearly 100% retention. Finally, the conductive elements (2, 14, 15) are within the housing (1) in

direct contact with the liquid non-conductives and are external to the housing (ie shown in 14, 15, Fig 6b) and are connected to external power via connector (18; Fig 8; additionally see above citations for discussion in specification). Since the electrical connectors (2, 14, 15) contact the non-conductives and the liquid non-conductives and additional travel outside the liquid impermeable housing (1) to be connected to power source (18) and this occurs via a seal between the housing and the electrical connectors and results in no leaking or loss of non-conductive fluid (see above citations), it is obvious and necessarily flows from Kuribayashi et al that the seal/bond created between the material forming the non-conductive housing and the conductive element is substantially liquid and moisture-impermeable.

(10) Response to Argument

The appellant argues:

1. Flower does not describe an electrically conductive element *integrally molded* within a reservoir housing in which an electrode end of the conductive element is positioned *within* the housing and a contact end of the conductive element is positioned *outside* the housing.

In response to (1), the Examiner notes that Fig 2 (shown below) explicitly shows an electrically conductive element (26) integrally molded within a reservoir housing (patch housing 4) in which an electrode end (end connecting to electrode 8) of the conductive element is positioned within the housing and a contact end (end connecting to 37 via conductive pad 34 - see Fig 1 of Flower) of the conductive element is positioned outside the housing. Furthermore, "integrally molded" is also this is product-by-process language and it doesn't appear to add any distinguishing features to the final product (see MPEP 2113).

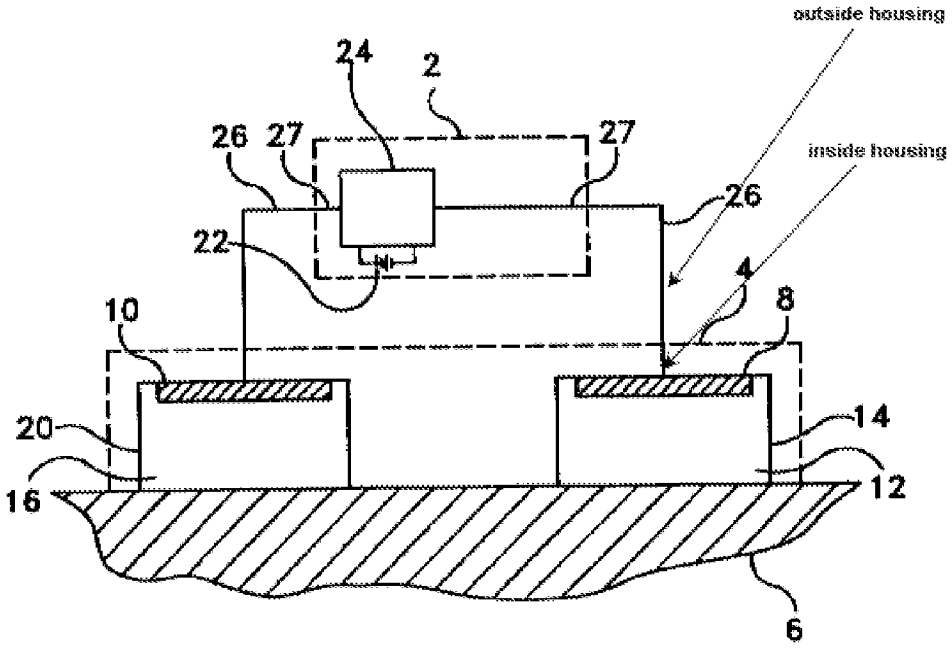


Figure 2 clearly shows the electrically conductive element (26) entering and extending into patch housing (4) which forms the housing (14) that defines the reservoir (12) and has an electrode tend that extends into housing (4) as shown to electrically connect to electrode (8). Further, the electrically conductive element (26) extends from electrode (8) from an inside of the housing, through the housing (4; Fig 1-2), to an outside of the housing to contact exposed conductive pads (34) positioned on the opposite edge of patch housing (4; Fig 1). The electrically conductive element (26) may be a printed flexible circuit, metal foils, wires, tabs, or electrically conductive adhesives (col 4, lns 27-31).

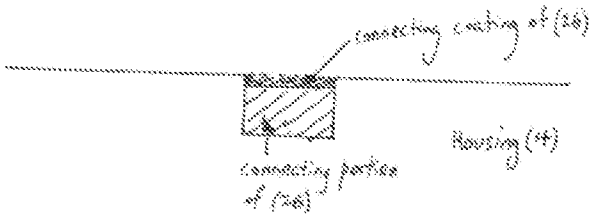
Even if Fig 2 is not dispositive, the Examiner notes that the appellant has not structurally claimed an electrode or contact end *in addition to* the electrically conductive element. Thus, the electrode (8) and conductive pad (34) are *part of the electrically conductive element.* See annotated drawing below an example.

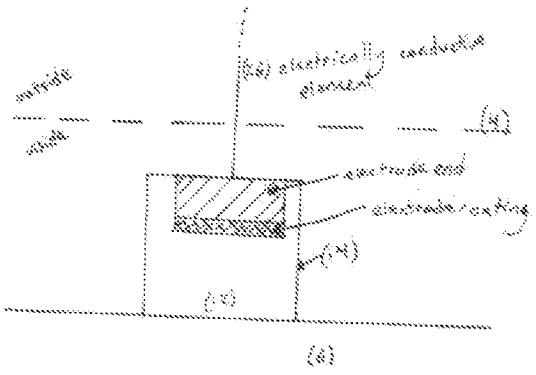
2. Flower does not describe an electrically conductive element in which an electrode end of the element is coated with an electrode coating, a contact end of the conductive element is coated with a contact coating comprising a flexible polymer.

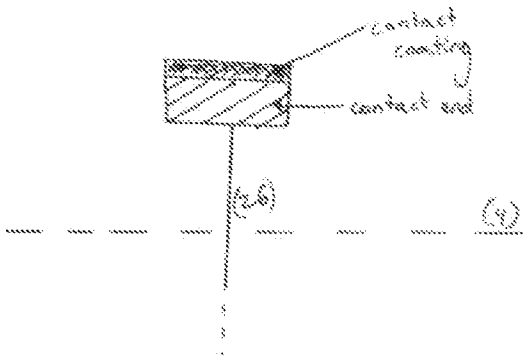
In response to (2), the Examiner first notes that in the appeal brief the appellant has provided mere allegation that Flower fails to describe the claim limitations. Appellant has not provided any argument or evidence in support of their allegation. The appellant has failed to show a clear error by the Examiner and the Board should affirm the Examiner accordingly.

The Examiner additionally notes that Flower discloses an electrically conductive element that can be a printed flexible circuit, metal foils, wires, tabs, or electrically conductive adhesives (col 4, lns 27-31). The appellant has not structurally claimed an electrode or contact end *in addition to* the electrically conductive element. Thus, the electrode (8) and conductive pad (34) may be considered as *part of the electrically conductive element.* Webster's defines a coating as "a layer of one substance covering another." The electrode end (8) is formed by a layer of conductive material that forms the electrically active electrode surface that contacts the contents of reservoir (12). The electrically conductive pad (34) also is formed by a layer of conductive material that forms the electrically active connection to the electrical conductor (27) on the controller. Each

forms a coating, a layer of one substance on top of another, which form an electrode end and contact end as shown in the annotated drawing shown below. The appellant has not defined the structure of the elements of the electrode end, connecting portion, or contact end and thus may be construed broadly so that a portion of each has an outer coating – a layer of one substance that covers another (and which may be the same substance – as shown by example in the drawings below. Flower discloses each and every claim limitation and as such the rejection must be affirmed.





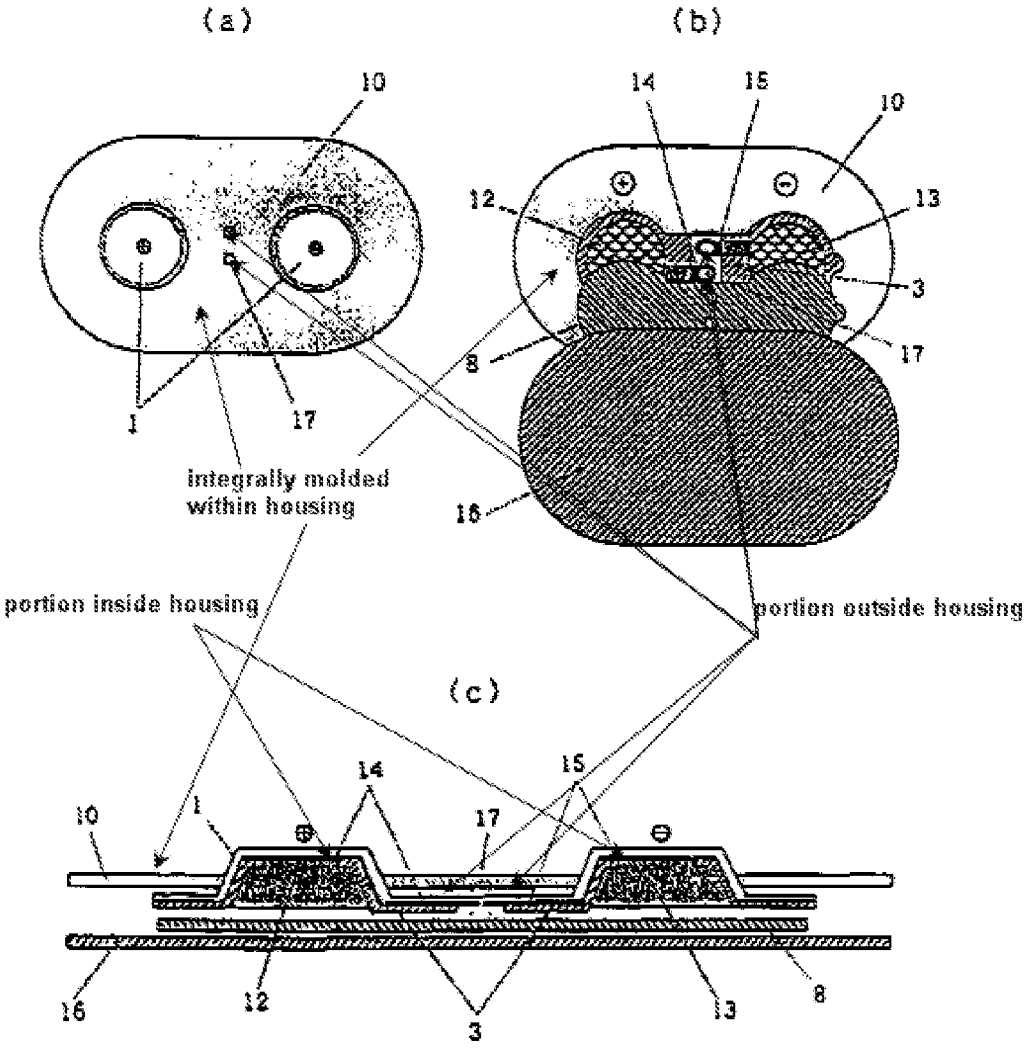


3. Kuribayshi's electrode layers 14 and 15 are necessarily *not integrally molded* within a non-conductive housing because the entirety of electrode layers 14 and 15 is on the inner portion of backing 1, and, thus, a first portion of the electrode layer is not located within a housing and a second portion of the electrode layer is not located on the outside of the housing.

In response to (3), the Examiner notes that a shown in the annotated drawings below - the backing (1) forms the basis of a reservoir housing capable of housing reservoirs (12, 13). It is apparent that electrode layers (14, 15) are integrally molded therein and run from an inside of the housing - where they form the electrodes in contact with the reservoirs (12, 13) - to an outside of the housing - where they form the electrical connection point at the insertion inlets (17) that are exposed outside the housing – where they connect to conductive snap connectors (19, 18) which connect the electrode layers to a power source. Again, the Examiner notes that the appellant has not structurally claimed an electrode or contact end *in addition to* the electrically conductive element. Thus, an electrode and a contact may be considered part of the electrically conductive element. Kuribayshi clearly shows an electrically conductive element integrally molded within a non-conductive housing (wherein integrally means "as a unit") that is located both inside and outside of the housing. The device clearly shown electrically conductive means (14, 15) that

connect to a power source outside the housing at a connection point (17), are integrally molding within the housing to run to a reservoir and electrically deliver current inside the reservoir (12, 13) to drive medicament into a patient. Furthermore, "integrally molded" is also this is product-by-process language and it doesn't appear to add any distinguishing features to the final product (see MPEP 2113).

Fig. 6



4. Kuribayshi does not describe an electrically conductive element in which an electrode end of the element is coated with an electrode coating, a contact end of

the conductive element is coated with a contact coating comprising a flexible polymer.

In response to (4), the Examiner first notes that in the appeal brief the appellant has provided mere allegation that Flower fails to describe the claim limitations. Appellant has not provided any argument or evidence in support of their allegation. The appellant has failed to show a clear error by the Examiner and the Board should affirm the Examiner accordingly.

The Examiner additionally notes that as disclosed in col 7, lns 1-5, 39-47 and col 8, lns 50-col 9, lns 15 Kuribayshi discloses the claimed materials and coatings - such as a conductive ink. Even if that disclose is not dispositive, the Examiner references and incorporates in full the interpretation and argument and drawings discussed above in response to appellant's argument (2). The appellants failure to structurally define the electrode end, connecting portion, and contact end once again allows the examiner to call an outermost surface layer (e.g. as shown in drawings above) as a the electrode, connecting, and contact coatings. Kuribayshi discloses each and every claim limitation and as such the rejection must be affirmed.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Andrew M Gilbert/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Janet C. Baxter/
TC 3700 TQAS